

**Remarks/Arguments:**

In response to the Office Action dated September 21, 2007, Applicants amend claims 1, 4 and 17-18 and cancel claims 2-3 without prejudice. The supports for the claim amendments can be found in the originally filed claims.

**35 U.S.C. §112, Second Paragraph Issues**

In the Office Action, the Examiner rejected claims 1-10 and 15-24 under 35 U.S.C. §112, second paragraph because the terms "electron-withdrawing groups," "C<sub>1-10</sub> divalent group..." and "C<sub>4-12</sub> divalent aromatic group" in the claims were deemed to be confusing. Even though Applicants disagree with the Examiner's position, to expedite the prosecution, Applicants amended these claims to eliminate the needs of mentioning these terms. The supports for these amendments can be found in the originally filed claims. Withdrawal of the rejection is respectfully requested.

In the Office Action, the Examiner rejected claims 17-18, second paragraph, because the terms "producing a compound" was deemed to be confusing. Applicants respectfully disagree with the Examiner's position. There is nothing confusing about "producing a compound." In addition, this term is in the preamble of the claim, which does not limit the scope of the claim unless it "breathes life" to the claim. In any case, to expedite the prosecution, Applicants delete these terms from the claims 17-18. Withdrawal of the rejection is respectfully requested.

**35 U.S.C. §112, First Paragraph Issues**

In the Office Action, the Examiner rejected claims 16 and 22-24 under 35 U.S.C. §112, first paragraph for failure to comply with the enablement requirement. Applicants respectfully traverse this rejection for the reasons below.

In support of the rejection, the Examiner averred that "the genes encoding CB receptors and FAAH appear to have been lost in insects, or their protein sequences mutated into unrecognizable pseudogenes..." However, the insect genes are not at issues here. The claims are limited to warm blooded animal and insects are not considered to be warm-blooded animals. Therefore, this particular statement cannot be used to support the Examiner's rejection.

In addition, the Examiner averred that even though Applicants have tested many compounds in the human CB1 and CB2 assays for activities, Applicants have not provided guidance or examples for the therapy of pain in a warm-blooded animal. Applicants respectfully disagree and submit that there has been a well-established link between CB1 activities and efficacy in treating pains in the literature. For example, Monhemius et al. stated in 2001: "[t]hese data

suggest that activation of cannabinoid CB1 receptor subtypes in GiA leads to behavioural analgesia." See Monhemius et al. "CB1 receptor mediated analgesia from the *Nucleus Reticularis Gigantocellularis pars alpha* is activated in an animal model of neuropathic pain," Brain Research, 908 (2001) 67-74. A copy of the article is included in the IDS filed together with the instant response. Therefore, Applicants respectfully submit that the link between CB1 activities and therapy of pain has been well established and, thus, the instant application provided ample guidance on therapy of pain.

Furthermore, Applicants submit that the numerous examples provided in the Application justified the breadth of the pending claims.

Therefore, Applicants submits that the Specification provided ample guidance and teaching to the claimed invention in view of the knowledge existed in the public literature.

In conclusion, in view of all the factors, Applicants submits claims 16 and 22-24 comply with 35 U.S.C. §112, first paragraph and withdrawal of the rejection is respectfully requested.

### **35 U.S.C. §102 Issues**

In the Office Action, the Examiner rejected Claims 1, 5-6, 15 and 19-21 under 35 U.S.C. §102(a) as being anticipated by Lau et al. WO 03/053938. Applicants respectfully traverse this rejection as far as it applies to the amended claims. The pending claims have been amended to require R<sup>F1</sup> and R<sup>F2</sup> to be independently selected from -CF<sub>3</sub>, -CH<sub>2</sub>CF<sub>3</sub>, -CH<sub>2</sub>CHF<sub>2</sub>, -CHF<sub>2</sub>CF<sub>3</sub>, -CHFCHF<sub>2</sub>, -CHFCH<sub>2</sub>F, -CF<sub>2</sub>CF<sub>3</sub>, -CF<sub>2</sub>CH<sub>3</sub>, -CF<sub>2</sub>CH<sub>2</sub>F, -CF<sub>2</sub>CHF<sub>2</sub>, -CF<sub>3</sub>, -CH<sub>2</sub>CCl<sub>3</sub>, -CH<sub>2</sub>CHCl<sub>2</sub>, -CH<sub>2</sub>CBr<sub>3</sub>, -CH<sub>2</sub>CHBr<sub>2</sub>, -CH<sub>2</sub>NO<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>NO<sub>2</sub>, -CH<sub>2</sub>CN, -CH<sub>2</sub>CH<sub>2</sub>CN, and -CH<sub>2</sub>CH<sub>2</sub>OCH<sub>3</sub>. Therefore, the pending claims no longer read on Lau et al. and withdrawal of the rejection is respectfully requested.

In the Office, the Examiner rejected claims 1 and 15 under 35 USC §102(a,e) as being anticipated by Cheng et al (WO 2002085866). Applicants respectfully traverse this rejection as far as it applies to the amended claims. The pending claims have been amended to require R<sup>F1</sup> and R<sup>F2</sup> to be independently selected from -CF<sub>3</sub>, -CH<sub>2</sub>CF<sub>3</sub>, -CH<sub>2</sub>CHF<sub>2</sub>, -CHF<sub>2</sub>CF<sub>3</sub>, -CHFCHF<sub>2</sub>, -CHFCH<sub>2</sub>F, -CF<sub>2</sub>CF<sub>3</sub>, -CF<sub>2</sub>CH<sub>3</sub>, -CF<sub>2</sub>CH<sub>2</sub>F, -CF<sub>2</sub>CHF<sub>2</sub>, -CF<sub>3</sub>, -CH<sub>2</sub>CCl<sub>3</sub>, -CH<sub>2</sub>CHCl<sub>2</sub>, -CH<sub>2</sub>CBr<sub>3</sub>, -CH<sub>2</sub>CHBr<sub>2</sub>, -CH<sub>2</sub>NO<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>NO<sub>2</sub>, -CH<sub>2</sub>CN, -CH<sub>2</sub>CH<sub>2</sub>CN, and -CH<sub>2</sub>CH<sub>2</sub>OCH<sub>3</sub>. Therefore, the pending claims no longer read on Cheng et al. and withdrawal of the rejection is respectfully requested.

### **Obvious Double Patenting**

In the Office Action, the Examiner rejected claims 1-10, 15-16 and 19-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of the USPN 7,030,139. Applicants respectfully traverse this rejection for the following reasons.

The Examiner based the *prima facie* obviousness of the instant claims on a conclusory statement that "[t]he instant claims 1-10, 15-16 and 19-21 are therefore fully embraced by the prior art claims" without giving further reasoning. However, whether "fully embraced" or not should not be the foundation of a *prima facie* obviousness rejection. In order to make a proper *prima facie* obviousness rejection, the Examiner carries the initial burden of showing that the reference(s) disclose every element recited in the pending claims and it would be obvious for a skilled person in the art to make the necessary changes or combination to arrive at the instant invention. A simple conclusory statement does not meet this burden.

In addition, the Examiner just averred, in the earlier 35 U.S.C. §112, first paragraph rejection, that the instant application was in a field of unpredictable arts. In the unpredictable arts, there must be some teaching, suggestion or motivation for making the necessary changes or combination in references before the Examiner can make the proper *prima facie* rejection. Therefore, the *prima facie* was improper for this additional reason.

In conclusion, the Examiner did not carry the initial burden of making a *prima facie* obviousness rejection and withdrawal of this rejection is respectfully requested.

**Conclusion**

Having now responded to all the rejections in the Office Action, Applicants believe the application is in condition for allowance, which action is respectfully requested.

A petition for a two month extension of time is being filed herewith, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 26-0166, referencing Attorney Docket No. 100831-1P US.

Respectfully submitted,  
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